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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,465	02/07/2005	Matthew H T Bui	306J-000220US	4663
20350 7590 06/08/2010 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834				
EXAMINER HARRIS, ALANA M				
ART UNIT		PAPER NUMBER		
1643				
MAIL DATE		DELIVERY MODE		
06/08/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/511,465

Applicant(s)

BUI ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1643

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 7-23 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 7-23 and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments and Amendments

1. Claims 1, 5, 7-23 and 26-28 are pending.

Claims 1, 14, 27 and 28 have been amended.

Claims 1, 5, 7-23 and 26-28 to the extent the CAIX is a polypeptide are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

3. The **NEW MATTER REJECTION** of claims 1, 5, 7-23 and 26-28 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of the amendments to claims 1, 14, 27 and 28 and the Remarks submitted February 18, 2010, see page 8, 3rd paragraph.

Maintained Rejections

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The rejection of claims 1, 5, 7-23 and 26-28 under 35 U.S.C. 103(a) as being unpatentable over Zavada et al./ U.S. Patent number 5,955,075 (issued September 21, 1999/ IDS reference 11 submitted March 31, 2005), and further in view of Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1657, March 15, 2001/ IDS reference 83 submitted March 31, 2005) and Beldegrun et al./ U.S. Patent Application Publication number 2002/0058041 A1 (published May 16, 2002) is maintained.

Applicants assert the claimed invention should receive benefit from U.S. Provisional Application Serial number 60/373,193, filed April 16, 2002. Applicants have assumed a 103(c) rejection should have been made based on the perceived priority date. Applicants' claimed invention is entitled to the priority date of April 15, 2003 because all the limitations of the claims were not of record in the provisional document, namely SEQ ID NO: 2 (human carbonic anhydrase IX (CAIX) protein), nor a method in which "...a quantification percentage of 85% stratifies the prognosis with a quantification percentage

lower than about 85%...'. Applicants assert support can be found in the said document on page 9, lines 11-17, but the Examiner does not concur, see Remarks, page 8, 4th paragraph. Moreover, Applicants should have known the 103(a) rejection was applied for this reason because Applicants are owners of all the applications related to the instant application. For this reason, the 103(a) rejection was applied and not a 103(c) rejection. Applicants' showing of common ownership does not overcome a rejection under 103(a), see MPEP 706.02(L)(2). For the reasons of record and set forth herein the rejection is maintained.

6. The rejection of claims 1, 5, 7-23 and 26-28 under 35 U.S.C. 103(a) as being unpatentable over WO 95/34650 (published December 21, 1995), and further in view of Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1657, March 15, 2001/ IDS reference 83 submitted March 31, 2005) and Beldegrun et al./ U.S. Patent Application Publication number 2002/0058041 A1 (published May 16, 2002) is maintained.

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Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a)

will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a *flexible schedule*, however she can normally be reached Monday through Saturday, between the hours of 8 am to 8 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
26 May 2010

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643